

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES  
ADVISORY COMMITTEE MEETING**

**18-19 JANUARY, 2001**

**TOPIC 2**

**Suitability Determination for Donors of Human Cells, Tissues, and Cellular and  
Tissue-Based Products: CJD and vCJD**

**CHARGE**

FDA asks the TSEAC to evaluate the risk of transmission of vCJD through the transplantation, implantation, infusion, or transfer of human cells, tissues, and cellular and tissue-based products, and compare this risk to that of the transfusion of blood and blood products, for which precautionary measures have already been adopted. Based upon this evaluation, and considering the potential effect on supply, the committee is asked to recommend whether FDA should defer donors of these cells and tissues who have possibly been exposed to the BSE agent through residence in or travel to BSE countries.

In addition, the TSEAC is asked to consider how information about residence/travel history can best be obtained. This is particularly relevant to the situation, in which corneas are procured under legislative consent. This term relates to state laws that allow the medical examiner or coroner to procure corneal tissue in the absence of consent of the donor's next of kin, and hence, in the absence of a donor medical history interview with the next of kin.